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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,079	10/19/2001	Gholam A. Peyman	41082	7267

1609 7590 12/15/2003

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on September 17, 2003
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-24 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr in combination with Warner et al and Yu et al. L'Esperance, Jr. teaches placing a lens implant on an exposed stromal surface and ablating the lens to the desired shape. Warner et al teach the desirability of producing a corneal flap, which is then replaced over a shaped stromal surface. Yu et al teach employing a robotic device to perform eye surgery. It would have been obvious to the artisan of ordinary skill to perform the method of L'Esperance, Jr. after forming a flap, since this preserves Bowman's layer, which is desirable, as taught by Warner et al and to perform various aspects such as the ablation, flap formation and implant placement using a robot, since this provides more accurate control, as taught by Yu et al, thus producing a method such as claimed.

Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. in combination with Warner et al and Yu et al as applied to claims 1-4 are above, and further in view of Salz. Salz teaches that the optical axis of the flap must be marked and its position assured and that the flap is smoothed after being replaced in a keratomyleusis procedure. It would have been obvious to the artisan of ordinary skill to mark the flap, since proper repositioning is critical to the outcome of the surgery and to similarly mark the implant since, if this were not also properly positioned, the proper positioning of the cornea would be to no avail, and to compress the corneal flap with a therapeutic contact such as a mild patch, since this maintains the corneal flap in position, thus producing a method such as claimed.

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Claims 9-14 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. in combination with Warner et al, Yu et al, and Salz as applied to claims 1 and 5-8 above, and further in view of Galvanauskas et al. Galvanauskas et al teach the desirability of using ultrashort pulses to form a corneal flaps. It would have been obvious to the artisan of ordinary skill to employ an ultrashort pulse laser to form the flap, since this provides a smooth cut, as taught by Galvanauskas et al, and to dispense the lens material using a plunger, since this is a notorious dispensing means in the medical field, is not critical, and provides no unexpected result, thus producing a method such as claimed.

Claims 15-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance, Jr. in combination with Warner et al, Yu et al, Salz and Galvanauskas et al. The teachings of L'Esperance, Jr.; Warner et al; Yu et al; Salz; and Galvanauskas et al and the motivations for combination thereof are essentially those already set forth above. Thus it would have been obvious, for the reasons already elucidated, to combine these old and well known teachings to produce a device such as claimed.

Applicant's arguments have been considered, but are not persuasive. It is argued that none of the references "actually discloses, teaches, or suggests inserting an inlay or a lens, or using a robotic arm to position an inlay relative to the cornea". The examiner firstly notes that L'Esperance Jr. clearly teaches placing a lens blank in contact with the stromal tissue of the cornea and then custom ablating that blank to provide the desired corneal curvature. As one of ordinary skill in the art will readily recognize, the process of L'Esperance Jr. will leave a corneal surface that is exposed stroma, with no epithelium and no Bowman's layer. As explicitly disclosed in Warner et al an object of the invention is to improve vision without surgically

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invading the central optically used region of the anterior surface of the cornea. Thus clearly one having ordinary skill would understand the desirability of maintaining the anterior surface inviolate when combining the methods of Warner et al and L'Esperance, Jr.

Regarding the teaching of Yu et al, the examiner respectfully notes that while several examples of devices are given, Yu et al do not limit their device to any particular tool. Further, as accurate placement is indispensable in the methods of both L'Esperance, Jr. and Warner et al, use of a highly accurate robotic apparatus would clearly enhance the accuracy of the operation.

Applicant's arguments filed September 17, 2003 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.



Shay/DI; November 20, 2003

DAVID M. SHAY  
PRIMARY EXAMINER  
GROUP 330